Knowledgeware Division
Advanced Automation Company
Yamatake Corporation

April 21, 2003

Docket Management Branch (HFA-305)

Food and Drug Administration

5630 Fishers Lane, rm. 1061

Rockville, MD 20852

SUBJECT: Comments on, "Guidance for Industry, Part 11, Electronic Records; Electronic Signatures – Scope and Application, Draft Guidance", Docket No. 03D-0060

Dear Sir or Madam:

The Knowledgeware Division of Yamatake Corporation is pleased to have the opportunity to provide comments on the above-referenced draft guidance. The Knowledgeware division is providing regulatory compliance consulting and computer system validation services to FDA-regulated companies in Japan.

In general, we believe that this draft guidance will contribute a better clarification of the interpretation of 21 CFR Part 11 provisions. For those of us who use English as a second language, the clarity of the language in the regulations and guidance is of vital importance. Our comments and recommendations are detailed on the attached pages.

Thank you for giving us the opportunity to express our views.

Sincerely yours,

Yamatake Corporation
Advanced Automation Company,
Knowledgeware Division
Masamitsu Watanabe
Division Manager

Address: Shin-urashima-cho 1-1-32
Kanagawa-ku, Yokohama
Japan, 221-0031
Tel: +81-45-461-8905
Fax: +81-45-461-8982

03D-0060 C 5

Sec.	Row(s)	Comments/Recommendations
II	72-73	**Withdrawal of Glossary Guidance** We believe the FDA original Glossary Guidance document was very useful in defining terms for which there were varied interpretations. We propose that the FDA consider again releasing the Glossary Guidance document to help ensure consistency in interpretation.
II	74-75	**Withdrawal of Time Stamps Guidance** Section 5.3 of the withdrawn Time Stamps guidance offered useful clarification on FDA's position on the time zone issue, clarifying for example the use of local time versus using a standard time reference. Please clarify FDA's position on this issue.
II	90-94	**Withdrawal of E-Copy guidance** Which part of the withdrawn guidance "may no longer be representative of FDA's approach under the new CGMP initiative"? We believe there were a number of good practices in those withdrawn guidance as well. For those outside the U.S., sources of information are usually limited to written formal announcements or documentation, and the lack of explanation of what had been wrong may likely lead to confusion. In some cases, withdrawal of all guidance was misunderstood as total cancellation of Part 11. We propose that some examples of items in the withdrawn guidance are added that did not agree with new CGMP approach.
III.A	236-239	**Clearer definition of Legacy Systems** We thought the term legacy was reserved only for those systems that were in use prior to 20 August 1997 and have not been subsequently modified or updated. The description in this paragraph indicates systems operable prior to August 20, 1997 are "legacy" systems, regardless of subsequent updates or modifications. As most systems may have been updated to address Y2K issues, and numerous software updates may have been made to keep the system operational, we expect more clarification on this point in the final guidance.

Sec.	Row(s)	Comments/Recommendations
III.C.3	238	**Legacy system** We believe the sentence "we will not normally take regulatory action" means that high-risk legacy systems are within the scope of Part 11. Please clarify in the final guidance if we are required to risk-assess retrospectively all the legacy systems when those systems maintain critical electronic records.
III.C.3	239-240	**Legacy systems – fit for intended use** Assuming that "fit for their intended use" indicates validation in the sentence "However, **all systems** must comply with all applicable predicate rule requirements and should be fit for their intended use", we propose not to use "all systems", because you do not have to validate all systems, but only those required by regulations
III.C.4 III.C.5	250-255, 276-279	**Record retention in paper form** While we are recommended to "supply copies of electronic records" in rows 250-255, we are not required to "archive required records in electronic format to non electronic media" in rows 276-279. It sounds contradictory and confusing. We propose to add to the sentence in row 250, "if records are maintained electronically."

Sec.	Row(s)	Comments/Recommendations
III.C.5	179-183 277-281	**Hybrid Systems** When paper records and electronic records coexist in a system, we understand all we need to do is to determine in advance if each record is electronic or paper, and then apply Part 11 only to the records used as electronic records. We understand that it means that we can have both Part 11-regulated records and non-regulated records within a system. We believe that some of the requirements of Part 11 are best met using a system wide perspective such as elements of security and validation, however requirements such as the audit trail would only apply to those records for which there is a predicate requirement and can best be enforced at the record level. As a result we feel requirements should be categorized as either system-wide or record specific.